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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,459	12/19/2001	Yasushi Watanabe	2500.9	2404
5514	7590	05/19/2004	EXAMINER	
FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			YOUNG, MICAH PAUL	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/913,459	Applicant(s) WATANABE ET AL.	
	Examiner Micah-Paul Young	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-35 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 15-35 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Acknowledgment of Papers Received: Request for Continued Examination

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 15-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Mizumoto et al (EP 0 745 382 hereafter '382) and Ohno et al (USPN 5,958,453 hereafter '453). The claims are drawn to a rapidly disintegrating intrabuccally tablet comprising two saccharides, a binder and a disintegrant. One saccharide is of high wettability against water while the other is of saccharide with high moldability.

4. The '382 patent discloses a rapidly disintegrating compressed tablet formulation comprising saccharides and active agents (abstract). The formulation comprises saccharides of

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both high and low moldability (pg. 5, lin. 20 – 28). Saccharides of low moldability include lactose, mannitol, and xylitol (*Ibid.*). Saccharides of high moldability include maltose, sorbitol, and oligosaccharides (*Ibid.*). The reference further discloses a method that comprises making a fluidized bed, spraying an aqueous solution comprising the components (saccharides + active agent), drying, forming granules and compressing the granules to make tablets (pg. 9, lin. 30-58).

5. What is lacking in the reference is a disclosure of binders or disintegrating compounds.

These compounds are well known in the art, and would be obvious to said artisan to include them into a tablet formulation. As seen in the '453 patent, it is very well known to include binders and disintegrants. Binders impart cohesive qualities to the powdered material, while disintegrators facilitate the breakup or disintegration of the tablet core during administration.

6. The '453 patent discloses a rapidly disintegrating buccal tablet comprising active agents, disintegrators and binders. Examples of binders include hydroxypropylcellulose (col. 6, lin. 1-4), and the disintegrators include crospovidone (col. 5, lin. 14-37). The formulation also includes saccharides as erythritol and mannitol (examples). The buccal tablets can be fluidized bed dried, and compression molded into tablet form (col. 6, lin. 43 – 51).

Also with regard to claims 15-20 which recited limitations as to how the tablets are obtained, these limitations are a process of making, yet a product is claimed. These claims are considered to be product-by-process claims, therefore these limitations are not considered. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious

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from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

With regard to claims reciting limitations as to the ratio of one type of saccharide to another, and concentration of the saccharides in the formulation, these limitations are not taken in to consideration. These recitations of optimal ranges can be determined through routine experimentation. The general combination of saccharides, binders, disintegrants, and surface-active agents is present in the prior art. It has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredients. However, the preparations of various compressed tablet formulations having various amounts of the actives is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *In re Russell*, 439 F.2d 1228, 169 USPQ 426 (CCPA 1971).

With these things in mind it would have been obvious to a skilled artisan to include the binder and disintegrators of ‘453 into the formulation of ‘382 in order to impart cohesiveness to the powdered materials and enhance the disintegration times. A skilled artisan would have been equally motivated to include the saccharide formulation of ‘453 into the formulation of ‘453 in order to improve disintegration time. The saccharides, binder and disintegrators would all improve the disintegration time of the resulting formulation and their combination is prima facie obvious. It is prima facie obvious to combine two compositions each of which is taught by the

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prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. *See In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). It would have been obvious to a skilled artisan to combine the saccharides of '382 into the formulation of '453 or the binders and disintegrators of '453 into the formulation of '382 with an expected result of a rapidly dissolving buccal tablet.

Response to Arguments

7. Applicant's arguments with respect to claims 15-25 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1615

MP Young

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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